DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN 1 2012

Re: CYSVIEW (previously Hexvix)
Patent Nos. 7,247,655 and 7,348,361
Docket Nos.: FDA-2011-E-0136
Docket No.: FDA-2011-E-0133

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 7,247,655, and 7,348,361 filed by Photocure ASA, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for CYSVIEW (previously Hexvix) (hexaminolevulinate hydrochloride), the human drug product claimed by the patents.

The total length of the regulatory review period for CYSVIEW is 3,103 days. Of this time, 2,770 days occurred during the testing phase and 333 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: November 30, 2001.

   The applicant claims October 29, 2001, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 30, 2001, which was 30 days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: June 30, 2009.

   FDA has verified the applicant's claim that the new drug application (NDA) for CYSVIEW (NDA 22-555) was submitted on June 30, 2009.

3. The date the application was approved: May 28, 2010.

FDA has verified the applicant's claim that NDA 22-555 was approved on May 28, 2010.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Deborah A. Somerville
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